

### **REMARKS**

Claims 31 and 33-52 are pending. Claims 50-52 are cancelled, without prejudice. Claims 53-58 are new. Support for new claims 53-58 amendment can be found, e.g., on page 46, lines 11-15, of the specification. The specification is amended at pages 23 and 24 to refer to the appropriate sequence identifiers, as required by the Examiner.

Applicants believe that no new matter is added by way of amendment.

I. **Sequence Rules**

The Examiner noted the present application does not comply with the sequence rules, in particular, on pages 23-34. Applicants have amended the specification on pages 23 and 24 to refer to the proper sequence identifiers. Applicants submit that the amended application now complies with the sequences rules

II. **Rejection of Claims 50-52 under 35 U.S.C. 112, First Paragraph**

The Examiner rejected claims 50-52 under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement. Claims 50-52 are canceled and the rejection is therefore moot as to these claims. The Examiner finds that the affinity measure recited only apply to monoclonals. Applicants have added claims 53 to 55 and 56 to 58 which depend from claims 40 and 42 respectively. As such, the rejection is overcome and may be properly withdrawn.

III. **Rejections of Claims 31 and 33-52 under 35 U.S.C. §112, First Paragraph**

The Examiner rejected Claims 31 and 33-49 under 35 U.S.C. §112, first paragraph on the basis that the epitopes of antibodies that ". . . do not bind to SEQ ID NO: 2, 4, 12, or 13 individually" are not described in the application. Claims 50-52 are canceled and the rejection is therefore moot as to these claims. Applicants respectfully disagree.

To meet the written description requirement, applicants must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she

was in possession of the invention (Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563-1564 (Fed. Cir. 1991)). In the case of antibodies, "as long as an applicant has disclosed a 'fully characterized antigen,' either by its structure, formula, chemical name, or physical properties, or depositing the protein in a public depository, the applicant can then claim an antibody by its binding affinity to that described antigen." (Noelle v. Lederman, 355 F.3d 1343, 1349 (Fed. Cir. 2004)). Therefore, the written description for an antibody is satisfied by fully characterizing an antigen so the antibody may be claimed by its binding affinity to that described antigen.

In the present application, Applicants have fully described the heterodimeric cytokine antigen of IL-B60 (SEQ ID NO: 2 or 4) and CLF-1 (SEQ ID NO: 12 or 13). Applicants also describe that "[i]mmunoselection, immunodepletion, and related techniques are available to prepare selective reagents, as desired, e.g., for the IL-B60 alone, or the complex between the subunits." (see, e.g., page 81, lines 29-32, of the specification).

Applicants respectfully point out that an invention does not have to be described *in ipsius verbis* or *in haec verba* in order to satisfy the written description requirement of 35 U.S.C. 112. See, e.g., Purdue Pharma L.P. v. Faulding Inc., 230 F.3d 1320, 1323 (Fed. Cir. 2000); and In re Wertheim, 191 U.S.P.Q. 90, 98 (CCPA 1976). Rather the disclosure must at least "reasonably convey to persons skilled in the art that the inventor had possession of the subject matter in question." See, e.g., Fujikawa v. Wattanasin, 93 F.3d 1559, 1570 (Fed. Cir. 1996). On page 28, lines 7-15, Applicants describe the combination of the two subunits to effectuate its biological activity.

Taken together, Applicants believe that the skilled artisan would reasonably believe that Applicants had possession of antibodies that bind to SEQ ID NO 2 or 4 in combination with SEQ ID NO: 12 or 13, but not to SEQ ID NO: 2, 4, 12, or 13 individually.

In view of the foregoing, Applicants respectfully request withdrawal of this rejection.

**Conclusion**

Applicants' current response is believed to be a complete reply to all the outstanding issues of the latest Office action. Further, the present response is a bona fide effort to place the application in condition for allowance or in better form for appeal. Accordingly, Applicants respectfully request reconsideration and passage of the amended claims to allowance at the earliest possible convenience.

Applicant believes that no additional fees are due with this communication. Should this not be the case, the Commissioner is hereby authorized to debit any charges or refund any overpayments to DNAX Deposit Account No. 04-1239.

If the Examiner believes that a telephonic conference would aid the prosecution of this case in any way, please call the undersigned.

Respectfully submitted,

Date: 19 December 2007

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